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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,484	04/25/2001	Paul L. DeAngelis	4605.003	2281

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/09/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,484

Applicant(s)

DEANGELIS, PAUL L.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-45,54,55,59,60,111-125 and 127-130 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.

- 6) ☒ Claim(s) 37-45,54,55,59,60,111-125 and 127-130 is/are rejected.

- 7) ☒ Claim(s) 42 is/are objected to.

- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other: .

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DETAILED ACTION

The following office action is a responsive to a telephone conversation with Douglas Sorocco on 3/14/03 in which a provisional election was made without traverse to prosecute the invention of Group I, claims 37-45,54,55,59,60,111-125,127-130. The response has the following effect:

- 1 The Election/Restriction has been provided.
2. Claims 37-45,54,55,59,60,111-125,127-130, the invention of Group I are prosecuted by the examiner.

Claims 97-106, 110, 126 are withdrawn. Claims 1-36, 46-53, 56-58, 61-96 and 107-109 are cancelled by preliminary amendment.

3. The responsive is contained herein below.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 37-45,54,55,59,60,111-125,127-130, drawn a chondroitin polymer, classified in class 536, subclass 55.1.
 - II. Claims 97-99, drawn to a dermatan polymer, classified in class 536, subclass 55.1.
 - III. Claims 100-102, drawn to a unsulfated chondroitin polysaccharide, classified in class 536, subclass 123.1, 55.1.
 - IV. Claims 103-106, 110, drawn to a polysaccharide, classified in class 536, subclass 123.1, 55.1

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V. Claims 126, drawn to a heterologous polypeptide, classified in class 435, subclass 183.

2. Inventions I to V are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions, or different effects (MPEP § 806.04, MPEP § 808.01)..

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Douglas Sorocco on 3/14/03 a provisional election was made without traverse to prosecute the invention of Group I, 37-45,54,55,59,60,111-125, 127-130. Affirmation of this election must be made by applicant in replying to this Office action. Claims 97-106, 110, 126 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant spoke with Michael C. Henry.

Claims 37-45,54,55,59,60,111-125,127-130 are pending in application

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Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Objections

Claims 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 42 applicant claims "The purified composition of claims 37, 38, 39, 40, 41, and 42, wherein the chondroitin polymer is represented by a structure". However, the phrase "and 42" fails to further limit the subject matter of any of the previous claims, 37, 38, 39, 40 or 41, since that phrase refers to claim 42. Claims 45,54,554,59,60 which depend on claim 42 are objected, because they depend on an objected claim (i.e. claim 42).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-41,43,44,45,111-125,127-130 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugumaran et al. (Journal of Biological Chemistry, (1997 May 30) 272 (22) 14399-403). Claim 37 is a product-by-process claim, wherein applicant claims "A purified composition, wherein the purified composition comprises a chondroitin polymer made by a

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recombinant process.” Sugumaran et al. disclose applicant’s purified composition, wherein the purified composition comprises a chondroitin polymer (see abstract; see 1st col., 2nd paragraph, page 14400). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order to further corroborate the reason for the aforementioned rejection. The quotation states that “PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).” It should be noted that claims 38-41, 43-45, 111-125, 127-130 which are drawn to chondroitin polymer or a composition comprising chondroitin polymer are also product-by-process claims and are also anticipated by Sugumaran et al.

Claims 42, 54, 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Casu et al. (US 5,008,253).

In claim 42, applicant claims “The purified composition of claims 37, 38, 39, 40, 41, and 42, wherein the chondroitin polymer is represented by a structure, (Beta-1,4-GlcUA-beta-1,3-GalNAC)_n wherein n is a positive integer greater than or equal to 1.” Casu et al. disclose chondroitin polymer (chondroitin 4- sulfate) with repeat units (Beta-1,4-GlcUA-beta-1,3-GalNAC) where n is greater than 1 (see col.2, last paragraph, to the table on col. 3 & 4. It should

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be noted that claims 54 and 59 are composition claims of the chondroitin polymer, and the location (in vitro or in vivo) where the chondroitin polymer becomes sulfated (as indicated in claims 54 and 59) does not further limit the claims.

Claims 42,55,60 are rejected under 35 U.S.C. 102(b) as being anticipated by Skjak-Braek et al. (US 4,990,601).

In claim 42, applicant claims "The purified composition of claims 37, 38, 39, 40, 41, and 42, wherein the chondroitin polymer is represented by a structure, (Beta-1,4-GlcUA-beta-1,3-GalNAC)_n wherein n is a positive integer greater than or equal to 1." Skjak-Braek et al. disclose applicant's chondroitin polymer (chondroitin sulfate) (see claim 9, col. 4). Claims 55 and 60 are drawn to chondroitin polymer that is epimerized (in vitro and in vivo, respectively). Skjak-Braek et al. disclose applicant's chondroitin polymer (chondroitin sulfate) that is epimerized (see claims 1 and 9, col. 4). It should be noted that claims 55 and 60 are composition claims of the chondroitin polymer that is epimerized, and the location (in vitro or in vivo) where the chondroitin polymer becomes epimerized (as indicated in claims 54 and 59) does not further limit the claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 4, 2003.



SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200